IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA AB, and AMYLIN PHARMACEUTICALS, LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. 14-1478-GMS (CONSOLIDATED)
TEVA PHARMACEUTICALS USA, INC.,	)	
Defendant.	)	

TEVA PHARMACEUTICALS USA, INC.'S FIRST AMENDED ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") hereby answers the Complaint ("the Complaint") filed by Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca AB and Amylin Pharmaceuticals, LLC (collectively, "Plaintiffs") in Civil Action No. 14-1478-GMS, which has been consolidated with Civil Action No. 15-050-GMS, by denying each and every allegation contained therein, except those that are specifically admitted, modified, or qualified in this Answer.

NATURE OF THE ACTION

1. No response is required from Teva USA to the extent that the allegations in paragraph 1 of the Complaint are solely to Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") or state conclusions of law. To the extent that the allegations are directed to Teva USA, Teva USA admits that Plaintiffs assert that this is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code. Teva USA admits that it filed Abbreviated New Drug Application ("ANDA") No. 205984 with the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, or sale of Exenatide

Injection 300mcg/1.2 mL and 600 mcg/2.4 mL (250 mcg/mL) ("Teva USA's ANDA Products"), which would be generic versions of Byetta®, prior to the expiration of U.S. Patent Nos. 6,858,576 ("the '576 patent"), 6,872,700 ("the '700 patent"), 6,956,026 ("the '026 patent"), 7,297,761 ("the '761 patent"), 6,902,744 ("the '744 patent"), 7,521,423 ("the '423 patent") and 7,741,269 ("the '269 patent").

THE PARTIES

2. Teva USA is without information sufficient to admit or deny the allegations in paragraph 2 of the Complaint and therefore denies the same.

3. Teva USA is without information sufficient to admit or deny the allegations in paragraph 3 of the Complaint and therefore denies the same.

4. Teva USA is without information sufficient to admit or deny the allegations in paragraph 4 of the Complaint and therefore denies the same.

5. Teva USA is without information sufficient to admit or deny the allegations in paragraph 5 of the Complaint and therefore denies the same.

6. Teva USA admits that it is a corporation organized and existing under the laws of the State of Delaware. Teva USA's principal place of business is at 1090 Horsham Road, North Wales, Pennsylvania 19454.

7. No response is required from Teva USA because the allegations in paragraph 7 of the Complaint are directed solely to Teva Ltd.

8. No response is required from Teva USA to the extent that the allegations in paragraph 8 of the Complaint are directed to Teva Ltd. or state conclusions of law. To the extent that the allegations are directed to Teva USA, Teva USA admits that it is an indirect wholly

owned subsidiary of Teva Ltd. Teva USA denies the remaining allegations of paragraph 8 of the Complaint to which a response is required.

9. No response is required from Teva USA to the extent that the allegations in paragraph 9 of the Complaint are directed to Teva Ltd. or state conclusions of law. To the extent that the allegations are directed to Teva USA, Teva USA denies the allegations of paragraph 9 of the Complaint to which a response is required.

JURISDICTION AND VENUE

10. No response is required from Teva USA to the extent that the allegations in paragraph 10 of the Complaint state conclusions of law. Teva USA admits that Plaintiffs purport to state claims that arise under the patent laws of the United States, including 35 U.S.C. § 271, for infringement of the '576, '700, '026, '744 and '423 patents (collectively, "the asserted patents"). Teva USA further admits that this Court has subject matter jurisdiction over Plaintiffs' allegations of infringement arising from Teva USA's filing of ANDA No. 205984 with a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification"). Teva USA denies the remaining allegations of paragraph 10 of the Complaint.

11. Teva USA does not contest that the Court has personal jurisdiction over it for purposes of this case. Teva USA admits that it is a Delaware corporation. Teva USA denies that its principal place of business is in Delaware.

12. No response is required from Teva USA to the extent that the allegations in paragraph 12 of the Complaint state conclusions of law. Teva USA does not contest that this Court has personal jurisdiction over it for purposes of this case. To the extent the remaining allegations in paragraph 12 of the Complaint are conclusions of law, no response is required

from Teva USA. Teva USA denies the remaining allegations of paragraph 12 of the Complaint to which a response is required.

13. Teva USA does not contest that this Court has personal jurisdiction over it for purposes of this case.

14. The allegations of paragraph 14 of the Complaint are directed solely to Teva Ltd. or state conclusions of law. To the extent a response is required from Teva USA, Teva USA denies the allegations of paragraph 14 of the Complaint.

15. No response is required from Teva USA to the extent that the allegations in paragraph 15 of the Complaint are directed to Teva Ltd. To the extent that the allegations are directed to Teva USA, Teva USA admits, for the purposes of this case, that this Court has personal jurisdiction over it. Teva USA denies the remaining allegations in paragraph 15 of the Complaint.

16. No response is required from Teva USA to the extent that the allegations in paragraph 16 of the Complaint are directed to Teva Ltd. or state conclusions of law. To the extent that the allegations are directed to Teva USA, Teva USA admits, for the purposes of this case, that venue with respect to Teva USA is proper in this judicial district.

PLAINTIFFS' PATENTS AND APPROVED BYETTA® DRUG PRODUCT

17. Upon information and belief, Teva USA admits that Byetta® (exenatide injection) is a prescription medicine that is FDA-approved "as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus." Teva USA is without information sufficient to admit or deny the remaining allegations in paragraph 17 of the Complaint and therefore denies the same.

18. Upon information and belief, Teva USA admits that the prescribing information for Byetta® indicates "[e]xenatide is a GLP-1 receptor agonist that enhances glucose-dependent insulin secretion by the pancreatic beta-cell, suppresses inappropriately elevated glucagon secretion, and slows gastric emptying." Teva USA is without information sufficient to admit or deny the remaining allegations in paragraph 18 of the Complaint and therefore denies the same.

19. Upon information and belief, Teva USA admits that, according to FDA's website: AstraZeneca AB is the holder of New Drug Application ("NDA") No. 021773 for Byetta® (300 mcg/1.2 mL and 600 mcg/2.4 mL (250 mcg/mL)); FDA initially approved NDA No. 021773 in April 2005; the initial prescribing information for Byetta® in April 2005 stated that "BYETTA is indicated as adjunctive therapy to improve glycemic control in patients with type 2 diabetes mellitus who are taking metformin, a sulfonylurea, or a combination of metformin and a sulfonylurea but have not achieved adequate glycemic control"; and, on October 30, 2009, FDA approved a supplement to NDA No. 021773 "for the use of Byetta® (exenatide) Injection as an adjunct to diet and exercise to improve glycemic control in adults with Type II diabetes mellitus." Teva USA is without information sufficient to admit or deny the remaining allegations in paragraph 19 of the Complaint and therefore denies the same.

20. Admitted.

21. Teva USA admits that the title of the '576 patent is "Methods for regulating gastrointestinal motility" and that the patent issued on or about February 22, 2005. Teva USA admits that the Orange Book lists January 6, 2017 as the expiration date for the '576 patent. Teva USA admits that what appears to be a true and correct copy of the '576 patent was attached to the Complaint as Exhibit A. Teva USA denies the remaining allegations of paragraph 21 of the Complaint.

22. Teva USA admits that the title of the ‘700 patent is “Methods for glucagon suppression” and that the patent issued on or about March 29, 2005. Teva USA admits that the Orange Book lists January 14, 2020 as the expiration date for the ‘700 patent. Teva USA admits that what appears to be a true and correct copy of the ‘700 patent was attached to the Complaint as Exhibit B. Teva USA denies the remaining allegations of paragraph 22 of the Complaint.

23. Teva USA admits that the title of the ‘026 patent is “Use of exendins for the reduction of food intake.” Teva USA admits that the Orange Book lists January 7, 2018 as the expiration date for the ‘026 patent. Teva USA admits that what appears to be a true and correct copy of the ‘026 patent was attached to the Complaint as Exhibit C. Teva USA denies the remaining allegations in paragraph 23 of the Complaint.

24. Teva USA admits that the ‘744 patent is titled “Exendin agonist formulations and methods of administration thereof” and that the patent issued on or about June 7, 2005. Teva USA admits that the Orange Book lists January 14, 2020 as the expiration date for the ‘744 patent. Teva USA admits that what appears to be a true and correct copy of the ‘744 patent was attached to the Complaint as Exhibit D. Teva USA denies the remaining allegations of paragraph 24 of the Complaint.

25. Teva USA admits that the ‘423 patent is titled “Exendin pharmaceutical compositions” and that the patent issued on or about April 21, 2009. Teva USA admits that the Orange Book lists October 15, 2017 as the expiration date for the ‘423 patent. Teva USA admits that what appears to be a true and correct copy of the ‘423 patent was attached to the Complaint as Exhibit E. Teva USA denies the remaining allegations of paragraph 25 of the Complaint.

26. Teva USA is without information sufficient to admit or deny the allegations in paragraph 26 of the Complaint and therefore denies the same.

DEFENDANT'S ANDA

27. No response is required from Teva USA to the extent that the allegations in paragraph 27 of the Complaint are directed to Teva Ltd. To the extent that the allegations are directed to Teva USA, Teva USA admits that before October 30, 2014, it submitted or caused to be submitted to the FDA ANDA No. 205984 with a Paragraph IV certification, seeking approval to engage in the commercial manufacture, use or sale of Teva USA's ANDA Products, which, if approved, will be generic versions of Byetta®, prior to the expiration of the '576, '700, '026, '761, '744, '423 and '269 patents. Teva USA denies any remaining allegations in Paragraph 29 of the Complaint.

28. No response is required from Teva USA to the extent that the allegations in paragraph 28 of the Complaint are directed to Teva Ltd. To the extent that the allegations are directed to Teva USA, Teva USA admits that by letter dated October 30, 2014 ("Notice Letter"), it notified Plaintiffs that Teva USA had submitted to the FDA ANDA No. 205984 and a Paragraph IV certification, seeking approval to engage in the commercial manufacture, use or sale of Teva USA's ANDA Products prior to the expiration of the '576, '700, '026, '761, '744, '423 and '269 patents. Teva USA denies any remaining allegations in paragraph 28 of the Complaint.

29. Teva USA admits that the Notice Letter states that "the '576, '700, '744, '026, '761, '423 and '269 patents are not valid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Teva USA's product." Teva USA denies any remaining allegations in paragraph 29 of the Complaint.

30. Denied.

31. No response is required from Teva USA to the extent that the allegations in paragraph 31 of the Complaint are directed to Teva Ltd. To the extent that the allegations are directed to Teva USA, Teva USA admits that it filed Teva USA's ANDA No. 205984 seeking FDA approval to sell Teva USA's ANDA Products in the United States. Teva USA denies the remaining allegations of paragraph 31 of the Complaint to which a response is required.

32. Denied

33. Denied.

34. To the extent that paragraph 34 of the Complaint states conclusions of law, no response is required from Teva USA. Teva USA admits that the Complaint was filed within forty-five days of Plaintiffs' receipt of the Notice Letter, but denies the remaining allegations of paragraph 34 of the Complaint to which a response is required.

COUNT I: CLAIM FOR INFRINGEMENT OF THE '576 PATENT

35. In response to the allegations contained in paragraph 35 of the Complaint, Teva USA incorporates each of the preceding paragraphs as if fully set forth herein.

36. No response is required from Teva USA to the extent that the allegations in paragraph 36 of the Complaint are directed to Teva Ltd. To the extent that the allegations are directed to Teva USA, Teva USA admits that it submitted or caused the submission of ANDA No. 205984 to FDA, and continues to seek FDA approval of ANDA No. 205984.

37. Denied.

38. No response is required from Teva USA to the extent that the allegations in paragraph 38 of the Complaint are directed to Teva Ltd. To the extent that the allegations are directed to Teva USA, Teva USA admits that it is seeking FDA approval for its ANDA No. 205984 for an indication "as an adjunct to diet and exercise to improve glycemic control in

adults with type 2 diabetes mellitus." Teva USA denies the remaining allegations of paragraph 38 of the Complaint.

39. Denied

40. No response is required from Teva USA to the extent that the allegations in paragraph 40 of the Complaint are directed to Teva Ltd. To the extent that the allegations are directed to Teva USA, Teva USA admits that it filed Teva USA's ANDA No. 205984 seeking FDA approval to sell Teva USA's ANDA Products in the United States with information providing instructions for using Teva USA's ANDA Products. Teva USA denies the remaining allegations of paragraph 40 of the Complaint.

41. No response is required from Teva USA to the extent that the allegations in paragraph 41 of the Complaint are directed to Teva Ltd. or state conclusions of law. To the extent that the allegations are directed to Teva USA, Teva USA admits that it was aware of the existence of the '576 patent when it filed ANDA No. 205984 with the FDA. Teva USA denies the remaining allegations of paragraph 41 of the Complaint to which a response is required.

42. No response is required from Teva USA to the extent that the allegations in paragraph 42 of the Complaint are directed to Teva Ltd. or state conclusions of law. Teva USA is without information sufficient to admit or deny the allegations in paragraph 42 of the Complaint and therefore denies the same.

COUNT II: CLAIM FOR INFRINGEMENT OF THE '700 PATENT

43. In response to the allegations contained in paragraph 43 of the Complaint, Teva USA incorporates each of the preceding paragraphs as if fully set forth herein.

44. No response is required from Teva USA to the extent that the allegations in paragraph 44 of the Complaint are directed to Teva Ltd. To the extent that the allegations are

directed to Teva USA, Teva USA admits that it submitted or caused the submission of ANDA No. 205984 to FDA, and continues to seek FDA approval of ANDA No. 205984.

45. Denied

46. No response is required from Teva USA to the extent that the allegations in paragraph 46 of the Complaint are directed to Teva Ltd. To the extent that the allegations are directed to Teva USA, Teva USA admits that it is seeking FDA approval for its ANDA No. 205984 for an indication "as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus." Teva USA denies the remaining allegations of paragraph 46 of the Complaint.

47. Denied.

48. No response is required from Teva USA to the extent that the allegations in paragraph 48 of the Complaint are directed to Teva Ltd. To the extent that the allegations are directed to Teva USA, Teva USA admits that it filed Teva USA's ANDA No. 205984 seeking FDA approval to sell Teva USA's ANDA Products in the United States with information providing instructions for using Teva USA's ANDA Products. Teva USA denies the remaining allegations of paragraph 48 of the Complaint.

49. No response is required from Teva USA to the extent that the allegations in paragraph 49 of the Complaint are directed to Teva Ltd. or state conclusions of law. To the extent that the allegations are directed to Teva USA, Teva USA admits that it was aware of the existence of the '700 patent when it filed ANDA No. 205984 with the FDA. Teva USA denies the remaining allegations of paragraph 49 of the Complaint to which a response is required.

50. No response is required from Teva USA to the extent that the allegations in paragraph 50 of the Complaint are directed to Teva Ltd. or state conclusions of law. Teva USA

is without information sufficient to admit or deny the allegations in paragraph 50 of the Complaint and therefore denies the same.

COUNT III: CLAIM FOR INFRINGEMENT OF THE '026 PATENT

51. In response to the allegations contained in paragraph 51 of the Complaint, Teva USA incorporates each of the preceding paragraphs as if fully set forth herein.

52. No response is required from Teva USA to the extent that the allegations in paragraph 52 of the Complaint are directed to Teva Ltd. To the extent that the allegations are directed to Teva USA, Teva USA admits that it submitted or caused the submission of ANDA No. 205984 to FDA, and continues to seek FDA approval of ANDA No. 205984.

53. Denied.

54. No response is required from Teva USA to the extent that the allegations in paragraph 54 of the Complaint are directed to Teva Ltd. To the extent that the allegations are directed to Teva USA, Teva USA admits that it is seeking FDA approval for its ANDA No. 205984 for an indication "as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus." Teva USA denies the remaining allegations of paragraph 54 of the Complaint.

55. Denied

56. No response is required from Teva USA to the extent that the allegations in paragraph 56 of the Complaint are directed to Teva Ltd. To the extent that the allegations are directed to Teva USA, Teva USA admits that it filed Teva USA's ANDA No. 205984 seeking FDA approval to sell Teva USA's ANDA Products in the United States with information providing instructions for using Teva USA's ANDA Products. Teva USA denies the remaining allegations of paragraph 56 of the Complaint.

57. No response is required from Teva USA to the extent that the allegations in paragraph 57 of the Complaint are directed to Teva Ltd. or state conclusions of law. To the extent that the allegations are directed to Teva USA, Teva USA admits that it was aware of the existence of the '026 patent when it filed ANDA No. 205984 with the FDA. Teva USA denies the remaining allegations of paragraph 57 of the Complaint to which a response is required.

58. No response is required from Teva USA to the extent that the allegations in paragraph 58 of the Complaint are directed to Teva Ltd. or state conclusions of law. Teva USA is without information sufficient to admit or deny the allegations in paragraph 58 of the Complaint and therefore denies the same.

COUNT IV: CLAIM FOR INFRINGEMENT OF THE '744 PATENT

59. In response to the allegations contained in paragraph 59 of the Complaint, Teva USA incorporates each of the preceding paragraphs as if fully set forth herein.

60. No response is required from Teva USA to the extent that the allegations in paragraph 60 of the Complaint are directed to Teva Ltd. To the extent that the allegations are directed to Teva USA, Teva USA admits that it submitted or caused the submission of ANDA No. 205984 to FDA, and continues to seek FDA approval of ANDA No. 205984.

61. Denied

62. Denied.

63. No response is required from Teva USA to the extent that the allegations in paragraph 63 of the Complaint are directed to Teva Ltd. or state conclusions of law. To the extent that the allegations are directed to Teva USA, Teva USA admits that it was aware of the existence of the '744 patent when it filed ANDA No. 205984 with the FDA. Teva USA denies the remaining allegations of paragraph 63 of the Complaint to which a response is required.

64. No response is required from Teva USA to the extent that the allegations in paragraph 64 of the Complaint are directed to Teva Ltd. or state conclusions of law. Teva USA is without information sufficient to admit or deny the allegations in paragraph 64 of the Complaint and therefore denies the same.

COUNT V: CLAIM FOR INFRINGEMENT OF THE '423 PATENT

65. In response to the allegations contained in paragraph 65 of the Complaint, Teva USA incorporates each of the preceding paragraphs as if fully set forth herein.

66. No response is required from Teva USA to the extent that the allegations in paragraph 66 of the Complaint are directed to Teva Ltd. To the extent that the allegations are directed to Teva USA, Teva USA admits that it submitted or caused the submission of ANDA No. 205984 to FDA, and continues to seek FDA approval of ANDA No. 205984.

67. Denied

68. Denied

69. No response is required from Teva USA to the extent that the allegations in paragraph 69 of the Complaint are directed to Teva Ltd. or state conclusions of law. To the extent that the allegations are directed to Teva USA, Teva USA admits that it was aware of the existence of the '423 patent when it filed ANDA No. 205984 with the FDA. Teva USA denies the remaining allegations of paragraph 69 of the Complaint to which a response is required.

70. No response is required from Teva USA to the extent that the allegations in paragraph 64 of the Complaint are directed to Teva Ltd. or state conclusions of law. Teva USA is without information sufficient to admit or deny the allegations in paragraph 70 of the Complaint and therefore denies the same.

ANSWER TO PRAYER FOR RELIEF

71. Teva USA denies each and every allegation contained in the Complaint not expressly admitted above. Teva USA denies that Plaintiffs are entitled to the judgment and relief prayed for in paragraphs (A)-(H) of the Complaint.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

72. Teva USA has not infringed and is not liable for infringement of the '576 patent, either literally or under the doctrine of equivalents.

SECOND AFFIRMATIVE DEFENSE

73. Teva USA has not infringed and is not liable for infringement of the '700 patent either literally or under the doctrine of equivalents.

THIRD AFFIRMATIVE DEFENSE

74. Teva USA has not infringed and is not liable for infringement of the '026 patent, either literally or under the doctrine of equivalents.

FOURTH AFFIRMATIVE DEFENSE

75. Teva USA has not infringed and is not be liable for infringement of the '744 patent, either literally or under the doctrine of equivalents.

FIFTH AFFIRMATIVE DEFENSE

76. Teva USA has not infringed and is not liable for infringement of the '423 patent, either literally or under the doctrine of equivalents.

SIXTH AFFIRMATIVE DEFENSE

77. Claims of the '576 patent are invalid pursuant to 35 U.S.C. §§ 101, 102 and 103 and for obviousness-type double patenting.

SEVENTH AFFIRMATIVE DEFENSE

78. Claims of the ‘700 patent are invalid pursuant to 35 U.S.C. §§ 101, 102, 103 and 112 and for obviousness-type double patenting.

EIGHTH AFFIRMATIVE DEFENSE

79. Claims of the ‘026 patent are invalid pursuant to 35 U.S.C. §§ 101, 102, 103 and 112 and for obviousness-type double patenting.

NINTH AFFIRMATIVE DEFENSE

80. Claims of the ‘744 patent are invalid pursuant to 35 U.S.C. §§ 101, 103 and 112 and for obviousness-type double patenting.

TENTH AFFIRMATIVE DEFENSE

81. Claims of the ‘423 patent are invalid pursuant to 35 U.S.C. §§ 101, 103 and 112.

ELEVENTH AFFIRMATIVE DEFENSE

82. AstraZeneca AB should be dismissed from this action for lack of standing because Plaintiffs have not averred in their Complaint that AstraZeneca AB has a right or interest in or to any of the asserted patents that is sufficient to confer AstraZeneca AB with standing to enforce the asserted patents against Teva USA.

TWELTH AFFIRMATIVE DEFENSE

83. Plaintiffs’ Complaint for Patent Infringement fails to state a claim upon which relief can be granted.

84. Teva USA specifically reserves the right to assert each and every other defense that may become evident during the course of discovery.

COUNTERCLAIM FOR DECLARATORY JUDGMENT

Counterclaim-Plaintiff Teva Pharmaceuticals USA, Inc. ("Teva USA"), for its counterclaim against AstraZeneca Pharmaceuticals LP ("AstraZeneca LP") and Amylin Pharmaceuticals, LLC ("Amylin") (collectively, "Counterclaim-Defendants"), alleges as follows:

NATURE OF THE ACTION

1. Teva USA incorporates by reference and realleges the allegations in paragraphs 1 through 84 of Teva USA's Answer set forth above as if fully set forth herein.

2. This is an action for a judgment declaring that claims of U.S. Patent Nos. 6,858,576 ("the '576 patent"), 6,872,700 ("the '700 patent"), 6,956,026 ("the '026 patent"), 6,902,744 ("the '744 patent") and 7,521,423 ("the '423 patent") are invalid, and that Teva USA has not infringed and will not infringe any valid and enforceable claim of the '576, '700, '026, '744 or '423 patent, either literally or under the doctrine of equivalents, by engaging in the commercial manufacture, use, offer for sale, sale or importation of Teva USA's ANDA Products that are the subject of ANDA No. 205984.

PARTIES

3. Counterclaim-Plaintiff Teva USA is a Delaware corporation with a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

4. Counterclaim-Defendant AstraZeneca LP has averred that it is a limited partnership organized under the laws of Delaware, and with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19850.

5. Counterclaim-Defendant Amylin has averred that it is an indirect, wholly-owned subsidiary of AstraZeneca PLC and is organized under the laws of the State of Delaware, with its principal place of business at 9625 Towne Centre Drive, San Diego, California 92121. Upon

information and belief, Amylin permanently maintains an agent in Delaware who is authorized by Amylin to receive service of process in this jurisdiction.

JURISDICTION AND VENUE

6. This is an action for a declaration that the claims of the '576, '700, '026, '744 and '423 patents are invalid and/or not infringed pursuant to the Patent Laws of the United States, 35 U.S.C. § 101 *et seq.* Accordingly, subject matter jurisdiction of this Court exists under the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and 28 U.S.C. §§ 1331 and 1338(a).

7. Counterclaim-Defendants have subjected themselves to the Court's personal jurisdiction by filing the Complaint in the above action in this Court.

8. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

FACTUAL BACKGROUND

9. The '576 patent, titled "Methods for regulating gastrointestinal motility," issued on or about February 22, 2005, and is listed in the Orange Book for Byetta®. A copy of the '576 patent was attached as Exhibit A to the Complaint of Counterclaim-Defendants and AstraZeneca AB.

10. The '700 patent, titled "Methods for glucagon suppression," issued on or about March 29, 2005, and is listed in the Orange Book for Byetta®. A copy of the '700 patent was attached as Exhibit B to the Complaint of Counterclaim-Defendants and AstraZeneca AB.

11. The '026 patent, titled "Use of exendins for the reduction of food intake," issued on or about October 18, 2005, and is listed in the Orange Book for Byetta®. A copy of the '026 patent was attached as Exhibit C to the Complaint of Counterclaim-Defendants and AstraZeneca AB.

12. The ‘744 patent, titled “Exendin agonist formulations and methods of administration thereof,” issued on or about June 7, 2005, and is listed in the Orange Book for Byetta®. A copy of the ‘744 patent was attached as Exhibit D to the Complaint of Counterclaim-Defendants and AstraZeneca AB.

13. The ‘423 patent, titled “Exendin pharmaceutical compositions,” issued on or about April 21, 2009, and is listed in the Orange Book for Byetta®. A copy of the ‘423 patent was attached as Exhibit E to the Complaint of Counterclaim-Defendants and AstraZeneca AB.

14. Counterclaim-Defendants have alleged in their Complaint that each of the ‘576, ‘700, ‘026, ‘744 and ‘423 patents is jointly owned by AstraZeneca LP and Amylin, that Counterclaim-Defendants have all right, title, and interest to the ‘576, ‘700, ‘026, ‘744, and ‘423 patents and are authorized to enforce them, and that Teva USA infringes or will infringe the ‘576, ‘700, ‘026, ‘744 and ‘423 patents.

15. Teva USA has submitted ANDA No. 205984 to the FDA requesting approval to engage in the commercial manufacture, use or sale of Teva USA’s ANDA Products. Teva USA’s ANDA No. 205984 included a Paragraph IV certification, seeking approval to engage in the commercial manufacture, use or sale of Teva USA’s ANDA Products prior to the expiration of the ‘576, ‘700, ‘026, ‘744 and ‘423 patents and two other patents.

16. By its Notice Letter dated October 30, 2014, Teva USA notified Counterclaim-Defendants that Teva USA had submitted to FDA ANDA No. 205984 with a Paragraph IV certification, seeking approval to engage in the commercial manufacture, use or sale of Teva USA’s ANDA Products prior to the expiration of the ‘576, ‘700, ‘026, ‘744 and ‘423 patents and two other patents on the basis that each of those patents was invalid, unenforceable, or would not be infringed by the commercial manufacture, use, or sale of Teva USA’s ANDA Products.

17. In their Complaint, Counterclaim-Defendants allege that that the ‘576, ‘700, ‘026, ‘744 and ‘423 patents are each listed in the Orange Book for Byetta® and further allege that Teva USA has infringed those five patents under 35 U.S.C. § 271(e)(2)(A) by virtue of having submitted ANDA No. 205984 with a Paragraph IV certification regarding those five patents, and that Teva USA’s commercial manufacture, use, sale, offer for sale or importation into the United States of Teva USA’s ANDA Products would infringe those five patents.

18. As a consequence of the ‘576, ‘700, ‘026, ‘744 and ‘423 patents being listed in the Orange Book with respect to Byetta®, Teva USA filing of ANDA No. 205984 with a Paragraph IV certification regarding those five patents and serving its Notice Letter on Counterclaim-Defendants, and the allegations of infringement of the ‘576, ‘700, ‘026, ‘744 and ‘423 patents made against Teva USA by Counterclaim-Defendants in their Complaint, there is an actual controversy between Counterclaim-Defendants and Teva USA, redressable by judgment of this Court, as to the non- infringement of the ‘576, ‘700, ‘026, ‘744 and ‘423 patents and the invalidity of claims of those patents.

COUNT I
Declaratory Judgment of Non-Infringement
United States Patent No. 6,858,576

19. Teva USA incorporates by reference and realleges the allegations in paragraphs 1 through 18 as if fully set forth herein.

20. An actual controversy exists between Teva USA and Counterclaim-Defendants concerning the non-infringement of the ‘576 patent, which requires a declaration of rights by this Court.

21. Teva USA has not infringed and is not liable for infringement of the ‘576 patent.

22. Teva USA is entitled to a declaratory judgment that Teva USA has not infringed and is not liable for infringement of any valid and enforceable claim of the ‘576 patent, and that

the commercial manufacture, use, offer for sale, sale or importation of Teva USA's ANDA Products would not infringe any valid and enforceable claim of the '576 patent, either literally or under the doctrine of equivalents.

COUNT II
Declaratory Judgment of Non-Infringement
United States Patent No. 6,872,700

23. Teva USA incorporates by reference and realleges the allegations in paragraphs 1 through 22 as if fully set forth herein.

24. An actual controversy exists between Teva USA and Counterclaim-Defendants concerning the non-infringement of the '700 patent, which requires a declaration of rights by this Court.

25. Teva USA has not infringed and is not liable for infringement of the '700 patent.

26. Teva USA is entitled to a declaratory judgment that Teva USA has not infringed and is not liable for infringement of any valid and enforceable claim of the '700 patent, and that the commercial manufacture, use, offer for sale, sale or importation of Teva USA's ANDA Products would not infringe any valid and enforceable claim of the '700 patent, either literally or under the doctrine of equivalents.

COUNT III
Declaratory Judgment of Non-Infringement
United States Patent No. 6,956,026

27. Teva USA incorporates by reference and realleges the allegations in paragraphs 1 through 26 as if fully set forth herein.

28. An actual controversy exists between Teva USA and Counterclaim-Defendants concerning the non-infringement of the '026 patent, which requires a declaration of rights by this Court.

29. Teva USA has not infringed and is not liable for infringement of the '026 patent.

30. Teva USA is entitled to a declaratory judgment that Teva USA has not infringed and is not liable for infringement of any valid and enforceable claim of the '026 patent, and that the commercial manufacture, use, offer for sale, sale or importation of Teva USA's ANDA Products would not infringe any valid and enforceable claim of the '026 patent, either literally or under the doctrine of equivalents.

COUNT IV
Declaratory Judgment of Non-Infringement
United States Patent No. 6,902,744

31. Teva USA incorporates by reference and realleges the allegations in paragraphs 1 through 30 as if fully set forth herein.

32. An actual controversy exists between Teva USA and Counterclaim-Defendants concerning the non-infringement of the '744 patent, which requires a declaration of rights by this Court.

33. Teva USA has not infringed and is not liable for infringement of the '744 patent.

34. Teva USA is entitled to a declaratory judgment that Teva USA has not infringed and is not liable for infringement of any valid and enforceable claim of the '744 patent, and that the commercial manufacture, use, offer for sale, sale or importation of Teva USA's ANDA Products would not infringe any valid and enforceable claim of the '744 patent, either literally or under the doctrine of equivalents.

COUNT V
Declaratory Judgment of Non-Infringement
United States Patent No. 7,521,423

35. Teva USA incorporates by reference and realleges the allegations in paragraphs 1 through 34 as if fully set forth herein.

36. An actual controversy exists between Teva USA and Counterclaim-Defendants concerning the non-infringement of the ‘423 patent, which requires a declaration of rights by this Court.

37. Teva USA has not infringed and is not liable for infringement of the ‘423 patent.

38. Teva USA is entitled to a declaratory judgment that Teva USA has not infringed and is not liable for infringement of any valid and enforceable claim of the ‘423 patent, and that the commercial manufacture, use, offer for sale, sale or importation of Teva USA’s ANDA Products would not infringe any valid and enforceable claim of the ‘423 patent, either literally or under the doctrine of equivalents.

COUNT VI
Declaratory Judgment of Invalidity
United States Patent No. 6,858,576

39. Teva USA incorporates by reference and realleges the allegations in paragraphs 1 through 38 as if fully set forth herein.

40. An actual controversy exists between Teva USA and Counterclaim-Defendants concerning the invalidity of claims of the ‘576 patent, which requires a declaration of rights by this Court.

41. Claims of the ‘576 patent are invalid pursuant to 35 U.S.C. §§ 101, 102 and 103 and for obviousness-type double patenting.

42. Teva USA is entitled to a declaratory judgment that claims of the ‘576 patent are invalid.

COUNT VII
Declaratory Judgment of Invalidity
United States Patent No. 6,872,700

43. Teva USA incorporates by reference and realleges the allegations in paragraphs 1 through 42 as if fully set forth herein.

44. An actual controversy exists between Teva USA and Counterclaim-Defendants concerning the invalidity of claims of the ‘700 patent, which requires a declaration of rights by this Court.

45. Claims of the ‘700 patent are invalid pursuant to 35 U.S.C. §§ 101, 102, 103 and 112 and for obviousness-type double patenting.

46. Teva USA is entitled to a declaratory judgment that claims of the ‘700 patent are invalid.

COUNT VIII
Declaratory Judgment of Invalidity
United States Patent No. 6,956,026

47. Teva USA incorporates by reference and realleges the allegations in paragraphs 1 through 46 as if fully set forth herein.

48. An actual controversy exists between Teva USA and Counterclaim-Defendants concerning the invalidity of claims of the ‘026 patent, which requires a declaration of rights by this Court.

49. Claims of the ‘026 patent are invalid pursuant to 35 U.S.C. §§ 101, 102, 103 and 112 and for obviousness-type double patenting.

50. Teva USA is entitled to a declaratory judgment that claims of the ‘026 patent are invalid.

COUNT IX
Declaratory Judgment of Invalidity
United States Patent No. 6,902,744

51. Teva USA incorporates by reference and realleges the allegations in paragraphs 1 through 50 as if fully set forth herein.

52. An actual controversy exists between Teva USA and Counterclaim-Defendants concerning the invalidity of claims of the '744 patent, which requires a declaration of rights by this Court.

53. Claims of the '744 patent are invalid pursuant to 35 U.S.C. §§ 101, 103 and 112 and for obviousness-type double patenting.

54. Teva USA is entitled to a declaratory judgment that claims of the '744 patent are invalid.

COUNT X
Declaratory Judgment of Invalidity
United States Patent No. 7,521,423

55. Teva USA incorporates by reference and realleges the allegations in paragraphs 1 through 54 as if fully set forth herein.

56. An actual controversy exists between Teva USA and Counterclaim-Defendants concerning the invalidity of claims of the '423 patent, which requires a declaration of rights by this Court.

57. Claims of the '423 patent are invalid pursuant to 35 U.S.C. §§ 101, 103 and 112.

58. Teva USA is entitled to a declaratory judgment that claims of the '423 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Teva USA respectfully requests that this Court grant the following relief against Counterclaim-Defendants:

A. A judgment declaring that Teva USA has not infringed and is not liable for infringement of any valid and enforceable claim of the '576, '700, '026, '744 or '423 patents, and that the commercial manufacture, use, offer for sale, sale or importation of Teva USA's

ANDA Products would not infringe any valid and enforceable claim of the ‘576, ‘700, ‘026, ‘744 or ‘423 patents, either literally or under the doctrine of equivalents;

B. A judgment declaring that claims of the ‘576, ‘700, ‘026, ‘744 and ‘423 patents are invalid;

C. An award to Teva USA of its costs and expenses in this action;

D. A determination that this is an exceptional case and an award to Teva of reasonable attorney fees and costs pursuant to 35 U.S.C. § 285; and

E. Such other and further relief as this Court may deem just.

/s/ John W. Shaw

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